



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/866,582	05/24/2001	George B. Witman	07917-145001 / UMMC 01-23	4483
26161	7590	11/07/2003	EXAMINER	
FISH & RICHARDSON PC 225 FRANKLIN ST BOSTON, MA 02110			DUFFY, PATRICIA ANN	
		ART UNIT	PAPER NUMBER	
		1645		
DATE MAILED: 11/07/2003				

20

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/866,582

Applicant(s)

WITMAN ET AL.

Examiner

Patricia A. Duffy

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 14 August 2003.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-36 is/are pending in the application.

4a) Of the above claim(s) 1-6 (in part) 7-36 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-6 (in part) is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) 1-36 are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. _____.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9 .

4) Interview Summary (PTO-413) Paper No(s). _____

5) Notice of Informal Patent Application (PTO-152)

6) Other: _____

DETAILED ACTION

The response filed 8-14-03 has been entered into the record.

Specification

The disclosure is objected to because of the following informalities:

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Information Disclosure Statement

The information disclosure statements filed January 31, 2002 and March 26, 2002 have been considered. Initialed copies are enclosed.

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892 or are cited on the PTO-1449's of record, they have not been considered.

Election/Restriction

Applicant's election without traverse of Group I, claims 1-7 in Paper No. 19 is acknowledged. It is however noted that the restriction requirement improperly grouped the polypeptides of claim 7, with the nucleic acids of Group 1. As such, claims 1-6 as drawn to nucleic acids, vectors and host cells of *Chlamydomonas* intraflagellar transport particle protein gene 20 are under examination. The examiner regrets this oversight.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

"Credible Utility" - Where an applicant has specifically asserted that an invention has a particular utility, that assertion cannot simply be dismissed by

Office personnel as being "wrong". Rather, Office personnel must determine if the assertion of utility is credible (i.e., whether the assertion of utility is believable to a person of ordinary skill in the art based on the totality of evidence and reasoning provided). An assertion is credible unless (A) the logic underlying the assertion is seriously flawed, or (B) the facts upon which the assertion is based is inconsistent with the logic underlying the assertion. Credibility as used in this context refers to the reliability of the statement based on the logic and facts that are offered by the applicant to support the assertion of utility. A *credible* utility is assessed from the standpoint of whether a person of ordinary skill in the art would accept that the recited or disclosed invention is currently available for such use. For example, no perpetual motion machines would be considered to be currently available. However, nucleic acids could be used as probes, chromosome markers, or forensic or diagnostic markers. Therefore, the credibility of such an assertion would not be questioned, although such a use might fail the *specific* and *substantial* tests (see below).

"*Specific Utility*" - A utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention. For example, a claim to a polynucleotide whose use is disclosed simply as a "gene probe" or "chromosome marker" would not be considered to be *specific* in the absence of a disclosure of a specific DNA target. Similarly, a general statement of diagnostic utility, such as diagnosing an unspecified disease, would ordinarily be insufficient absent a disclosure of what condition can be diagnosed.

"*Substantial utility*" - a utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. For example, both a therapeutic method of treating a known or newly discovered disease and an assay method for identifying compounds that themselves have a "substantial utility" define a "real world" context of use. An assay that measures the presence of a material which has a stated correlation to a predisposition to the onset of a particular disease condition would also define a "real world" context of use in identifying potential candidates for preventive measures or further monitoring. On the other hand, the following are examples of situations that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use and, therefore, do not define "substantial utilities":

- A. Basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved.
- B. A method of treating an unspecified disease or condition. (Note, this is in contrast to the general rule that treatments of specific diseases or conditions meet the criteria of 35 U.S.C. § 101.)

Art Unit: 1645

C. A Method of assaying for or identifying a material that itself has no "specific and/or substantial utility".

D. A method of making a material that itself has no specific, substantial, and credible utility.

E. A claim to an intermediate product for use in making a final product that has no specific, substantial, and credible utility.

Note that "throw away" utilities do not meet the tests for a *specific or substantial utility*. For example, using transgenic mice as snake food is a utility that is neither specific (all mice could function as snake food) nor substantial (using a mouse costing tens of thousands of dollars to produce as snake food is not a "real world" context of use). Similarly, use of any protein as an animal food supplement or a shampoo ingredient are "throw away" utilities that would not pass muster as specific or substantial utilities under 35 U.S.C. § 101. This analysis should, of course, be tempered by consideration of the context and nature of the invention. For example, if a transgenic mouse was generated with the specific provision of an enhanced nutrient profile, and disclosed for use as an animal food, then the test for specific and substantial *asserted utility* would be considered to be met.

"Well established utility" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art. "Well established utility" does not encompass any "throw away" utility that one can dream up for an invention or a nonspecific utility that would apply to virtually every member of a general class of materials, such as proteins or DNA. If this is the case, any product or apparatus, including perpetual motion machines, would have a "well established utility" as landfill, an amusement device, a toy, or a paper weight; any carbon containing molecule would have a "well established utility" as a fuel since it can be burned; any protein would have well established utility as a protein supplement for animal food. This is not the intention of the statute.

Claims 1-6 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

The claims are drawn to nucleic acid genes encoding nucleic acids, vectors and host cells of *Chlamydomonas* intraflagellar transport particle protein gene 20. The teachings of the specification are limited to a sequence of SEQ ID NO:1 which encodes a polypeptide of SEQ ID NO:2. The claimed nucleic acids, vectors and host cells are not supported by a specific asserted utility because the disclosed uses of the nucleic acids encoding proteins are not specific and substantial or well

established. The specification fails to set forth the actual function of the particle transport protein gene 20 and alleges that homologs are present in mammals, but fails to identify any homologs for this specific gene. The specification at pages 4-7 describe the potential uses of the nucleic acid and particle protein gene 20. The specification contemplates that nucleic acids encoding the *Chlamydomonas* particle protein gene 20 can be used. These uses are: A) methods of identifying a candidate compound that modulates (inhibits or stimulates) the activity of the protein by means of determining whether the compound interacts with the protein wherein interaction indicates that the compound is a candidate modulator, B) methods to identify a candidate compound that restores the activity of a defective or absent human intraflagellar transport particle protein, C) methods of diagnosing a disorder in a tissue in a subject that is associated with a defective or absent human intraflagellar transport particle protein, D) methods of treatment of a disorder in a subject by administering the subject a human IFT particle polypeptide by means of the encoding nucleic acid, and E) methods of identifying compounds that inhibit or restore IFT function by screening for small molecules that bind to the polypeptide.

As to asserted utilities A) and E), the specification fails to teach the actual biological activity of the claimed polypeptide encoded by *Chlamydomonas* particle protein gene 20. The specification fails to teach the corresponding human/mammalian homolog of this *Chlamydomonas* particle protein 20 gene. As such, it is unclear how the skilled artisan would be able to assess modulation (stimulation or inhibition) by means of mere binding of an agent to the polypeptide. The actual interaction sites of the *Chlamydomonas* particle protein gene 20 with other intraflagellar transport proteins has not been taught by the specification and therefore the skilled artisan would not be able to ascertain if mere binding to any random site on the polypeptide would be a positive, negative or null event. Binding does not discriminate, stimulators from inhibitors from null events. Therefore, the binding assays described in the specification can not provide information regarding stimulation or inhibition in the absence of any type of specifically described or assayed biological activity. Screening for inhibitors or modulators or binding agents of the protein is a non-specific use that is general and is not particular to the proteins being claimed. The specification does not identify a readily screenable in vitro activity of the protein per se, nor does it demonstrate a direct correlation of the screenable activity with any biological function or disease state. The function of the protein encoded by the claimed nucleic acid in intraflagellar transport is not specifically set forth in the specification as filed. The specification fails to teach, and the art is devoid of any teaching that the *Chlamydomonas* particle proteins can complement or replace their inactive mammalian counterpart and therefore any generic asserted use of the nucleic acid encoding the polypeptide is not specific or substantial. Not specific because it can apply to any nucleic acid encoding any polypeptide. It is not substantial because one skilled in the art would have to

discover the actual activity of the polypeptide prior to screening to be able to distinguish modulators of activity from null binding events. Identifying and studying the properties of a protein itself or the potential activity in intraflagellar transport mechanism in which the protein is involved does not define a "real world" context or use.

As to asserted utility B), there is no teaching of any disease or disorder that relates to a lack or over activity of *Chlamydomonas* particle protein gene 20 nor any indication of how this relates to any human disorder as such, the asserted utility is not specific because it does not identify a specific targeted disorder and it is not substantial because there is no teaching that a *Chlamydomonas* protein can be used or substituted for the alleged mammalian homolog. The specification lacks teaching of functional substitution of one for the other and one of skill in the art would have to carry out further research to identify the disease and perform further research to confirm this use.

As to asserted utilities C) and D), the claims are drawn to nucleic acids encoding *Chlamydomonas* particle protein 20 gene. The specification does not teach any human disease that has a defective particle protein 20 gene. As such, the use of nucleic acids encoding a *Chlamydomonas* particle protein gene for the diagnosis or treatment of an undefined disorder is not specific. The method of treatment is also not substantial because there is no teaching that the *Chlamydomonas* particle proteins and genes are readily interchangeable with the alleged human or mammalian counterparts. One of skill in the art would have to carry out further research to reasonably confirm that such a use is possible. The requirement for such further research indicates that the specification, at the time of filing, has failed to provide a real world use for the claimed nucleic acid for the treatment of a disease or disorder.

Similarly, the other listed and asserted utilities as summarized above or in the instant specification are neither substantial nor specific due to being generic in nature and applicable to a myriad of such compounds. Note, because the nucleic acids encoding *Chlamydomonas* particle protein 20 of claimed invention is not supported by a specific and substantial asserted utility or well established utility for the reasons set forth above, credibility has not been assessed.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The claims are drawn to nucleic acid genes, encoding nucleic acids that are 90% identical to *Chlamydomonas* intraflagellar transport particle protein gene 20, vectors and host cells of *Chlamydomonas* intraflagellar transport particle protein gene 20 that has no structure. These claims are not viewed as limited by either specific nucleic acid structure or function. The claimed nucleic acids have no recited structure and the recitation of *Chlamydomonas* intraflagellar transport particle protein gene 20 does not convey a particular structure to the skilled artisan and does not distinguish the instantly claimed nucleic acid from any other nucleic acid and therefore the claims encompass an infinite number of polypeptides with infinite variation. The specification discloses a single nucleic acid (SEQ ID NO:1) that encodes a *Chlamydomonas* intraflagellar transport particle protein (SEQ ID NO:2). Neither of these two structures are present in the claims. The recitation of " *Chlamydomonas* intraflagellar transport particle protein gene 20" does not convey a common structure or function. The scope of the claims includes innumerable structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. The specification and the claims do not provide any guidance on the structure of the polypeptide and what changes can or can not be made. Structural and functional features that could distinguish compounds in the genus from others in the protein class are missing from the disclosure and the claims. No common structural attributes identify the members of the genus. No common function identifies the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description, because specific, not general

Art Unit: 1645

guidance is needed. Since the disclosure fails to describe the common attributes or structural characteristics that identify members of the genus, and because the genus is highly variant, the function of the binding of antibody alone is insufficient to describe the genus of nucleic acids encoding polypeptides of that function equivalently. One of skill in the art would reasonable conclude that the disclosure of a single SEQ ID NO:1, fails to provide a representative number of species to describe the claimed genus especially as it relates to fragments of a gene.

Applicants were not in possession of the claimed genus because the specification does not convey to one of skill in the art a representative number of variants in structure and function of any such polypeptide that has the claimed/structure and function. The genus of nucleic acids encoding polypeptides is substantial and highly variant because the polypeptides do not have a common structure and function. The recitation of "Chlamydomonas intraflagellar transport particle protein" does not convey a common structure nor a common function. There is no assay or function in the specification that measures intraflagellar transport by using particle protein gene 20 and is not defined in the specification as filed. As such, generic polypeptide sequences that are unrelated via structure and function are highly variant and not conveyed by way of written description by the specification at the time of filing. As such the specification lacks written description for the highly variant genus of nucleic acids encoding polypeptides and one skilled in the art would not recognize that applicants had possession of the genus of claimed nucleic acids, vectors and host cells as instantly claimed.

As to the recitation of "gene", the specification has not described nor disclosed the nucleic acid for the claimed "Chlamydomonas intraflagellar transport particle protein 20 gene". As to the gene elements, a functional gene encompasses much more than a protein coding region (see Davis et al., Microbiology, page 267). A gene is conventionally associated with positive and negative controlling elements without which no protein is expressed. A gene is also broadly defined in the art as a segment of DNA involved in the production of a polypeptide chain which includes regions preceding and following the coding regions (i.e. leader and trailer) as well as regions in between individual coding segments (i.e. introns; see Lewin, B., GENES IV, Oxford University Press, 1990, page 810). The specification fails to describe a functional gene *per se* and as such, one skilled in the arts would recognize that Applicants were not in possession of the nucleic acid encoding the gene, variants, or fragments as are now claimed.

Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claim 1 and dependent claims 3, 4, 5 and 6, the claims are indefinite because the recite percent identity of a nucleic acid to a sequence whose specific

Art Unit: 1645

amino acid or nucleic acid structure is undefined. As such, one skilled in the art would not be able to ascertain the metes and bounds of the claimed nucleic acids, vectors and host cells.

As to claim 1 and every claim dependent thereon (2-6) the claims are *prima facie* indefinite in the recitation of "particle protein 20 gene" does not define the nucleic acid as such the metes and bounds of the particle protein 20 gene can not be ascertained, nor would the skilled artisan be readily apprised of the metes and bounds of the claimed nucleic acids, genes, variants and fragments.

Claim Rejections - 35 USC § 102 and 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Prior to setting forth the art rejections, it is noted that the claimed nucleic acids, vectors and host cells lacked utility, written description and enablement in provisional application 60/206,923, filed on May 24, 2000. As such, the prior art date assigned to the claimed invention is the instant filing date of May 24, 2001.

Claims 1 and 2 are rejected under 35 U.S.C. 102(a) as being anticipated by Grossman et al., (Accession Number BE352290, July 18, 2000).

Grossman et al teach a 493 base pair cDNA clone that encodes a xpress d sequence tag from *Chlamydomonas reinhardtii*. The *Chlamydomonas reinhardtii*

Art Unit: 1645

nucleic acid encodes a polypeptide with at 100% identity with at least 45 consecutive amino acids with a structurally undefined protein 20 gene (see attached alignment). Therefore, Grossman et al meets the limitations of the nucleic acid claims with respect to "a sequence 90% identical to a sequence", a complement, 15 a sequence encoding consecutive nucleic acid residues, a nucleic acid encoding a polypeptide comprising 10 consecutive amino acids as compared to an undefined sequence and the structurally undefined particle protein 20 gene or a complement thereof as recited in claim 2.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Asamizu et al, (DNA Res, 6(6):369-373, 1999).

Asamizu et al teach a 466 base pair cDNA clone that encodes a non-redundant expressed sequence tag from *Chlamydomonas reinhardtii*. The *Chlamydomonas reinhardtii* nucleic acid encodes a polypeptide with at 100% identity with at least 110 consecutive amino acids with a structurally undefined protein 20 gene (see attached alignment). Therefore, Asamizu et al meets the limitations of the nucleic acid claims with respect to "a sequence 90% identical", a complement, 15 consecutive nucleic acid residues, a nucleic acid encoding a polypeptide comprising 10 consecutive amino acids as compared to an undefined sequence and the structurally undefined particle protein 20 gene or a complement thereof as recited in claim 2.

Claims 3-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grossman et al (Accession Number BE352290, July 18, 2000) or Asamizu et al, (DNA Res, 6(6):369-373, 1999) as applied to claims 1 and 2 above either in view of Campbell (Monoclonal Antibody Technology, Elsevier Science Publishing Company, Inc., page 28, column 2, third paragraph) and Sambrook et al (Molecular Cloning A Laboratory Manual, Second Edition, Cold Spring Harbor Laboratory Press, 1989, pages 16.1-16.81).

Grossman et al (Accession Number BE352290, July 18, 2000) and Asamizu et al, (DNA Res, 6(6):369-373, 1999) are set forth supra. The references differ by not teaching the isolated nucleic acid further comprising nucleic acid sequences encoding a heterologous polypeptide or in a host cell.

Campbell et al teaches that "It is customary now for any group working on a macromolecule to both clone the genes coding for it and make monoclonal antibodies to it (sometimes without a clear objective for their application.)"

Sambrook et al teach means of expression of proteins from cloned genes in non-human mammalian cells (i.e. simian COS cells; page) and teach that expression of protein from cloned eukaryotic genes in mammalian cells have a number of different purposes (see paragraph bridging pages 16.3-16.4) such as produce large amount of proteins of biological interest, to study the biosynthesis and intracellular

transport of prot in following their expression in a variety of cell types, to elucidate structure-function relationships by analyzing the properties of normal and mutant prot ins. Sambrook et al teach conventional textbook means and methods for making expression vectors comprising the isolated cloned genes and expression in a non-human mammalian host cell (see entire chapter 3, pages 16.1-16.81). Sambrook et a teach that the cloning vectors comprise heterologous genes that encode polypeptides as selectable markers such as thymidine kinase, dihydrofolate reductase etc (pages 16.9-16.15).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time that the invention was made to insert the cloned nucleic acid of either Grossman et al (Accession Number BE352290, July 18, 2000) or Asamizu et al, (DNA Res, 6(6):369-373, 1999) into an selectable expression vector according to Sambrook et al in order to express the polypeptide to make antibodies because Campbell et al teaches that it is customary to make monoclonal antibodies to macromolecules even without a clear objective for their application or for any of the plethora of reasons set forth in Sambrook as discussed above. Further, the combination meets the limitation of the selectable markers are polypeptides encoded by genes that are heterologous to that of cloned nucleic acid of Grossman et al or Asamizu et al. As such, all claims are rendered obvious.

Status of the Claims

Claims 1-6 stand rejected.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 703-305-7555. Please note that the Patent and Trademark Office is moving to a new location on or about January 26, 2004. After this date the telephone number of the undersigned examiner will be 571-272-0855. The examiner can normally be reached on M-F 9:30pm-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Smith Lynette can be reached on 703-308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Application/Control Number: 09/866,582
Art Unit: 1645

Page 12

Patricia A. Duffy
Patricia A. Duffy, Ph.D.

Primary Examiner

Art Unit 1645

Patricia A. Duffy, Ph.D.
November 4, 2003